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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/970,049 | 10/02/2001 | Chih-Ming Chen | 300.1033US | 8670 |

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| EXAMINER | |
|---|---|
| OH, SIMON J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1618 | |

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/970,049 | CHEN, CHIH-MING | |
| | Examiner | Art Unit | |
| | Simon J. Oh | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Papers Received*

Receipt is acknowledged of the applicant's amendment, response, and petition for extension of time, all received on 20 April 2006.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 45 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, it is not clear from where the specific embodiment as a whole described in Claim 45 draws support from the instant specification. The particular combination of (1) the selection of the two specific drugs, each with (2) their respective dosage amounts, being (3) specifically arranged as 7 capsules and 14 tablets does not appear to be clearly described in the original disclosure. The examiner respectfully requests from where the invention as embodied by Claim 45 is specifically disclosed in the instant specification.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 35-44 under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Källgren, Depui *et al.*, and Eek is rendered moot with the cancellation of these claims.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Källgren, Depui et al., and Eek.

The Källgren patent teaches blister pack comprising at least a first and second row of blisters, perforated in such a way that individual blisters may be individually separated from the pack (See Abstract; Column 2, Lines 38-52; and Figures). The disclosed blister pack may be used for drugs such as omeprazole. Additionally, the blister pack is useful for packaging drugs that should be administered in combination (See Column 3, Lines 4-41).

The Källgren patent does not explicitly teach the use of the disclosed pack with a combination of a proton pump inhibitor and a non-steroidal anti-inflammatory drug.

The Depui *et al.* patent teaches a drug combination comprising a proton pump inhibitor and a non-steroidal anti-inflammatory drug (See Abstract). Omeprazole and lansoprazole are listed as suitable proton pump inhibitors; naproxen is listed as a suitable non-steroidal anti-inflammatory drug (See Column 6, Line 1 to Column 8, Line 13). A tablet comprising lansoprazole and naproxen is disclosed (See Example 4). The use of these drugs in separate dosage forms in a combination therapy in the prior art is acknowledged in the disclosure (See

Column 2, Lines 32-40). Suitable dosage ranges for each category are listed; each dosage form will preferably comprise 10 to 80 mg of the proton pump inhibitor and 10 to 800 mg of the non-steroidal anti-inflammatory drug (See Column 14, Lines 7-25)

The Eek document discloses drug packaging consisting of blister pack cards that may be assembled to form a combination pack of dosage forms, such as tablets (See Abstract; Page 1, Lines 5-12; and Figures). The scope of the disclosed invention encompasses dosage units of different drugs or different amounts of drugs within a single blister pack (See Page 5, Lines 8-14). Digital notation may be printed on the pack for the benefit of the patient. Alternatively, other notation may be printed, such as the time of day or the day of the week for the dose to be taken (See Page 7, Lines 7-11). Methods of treating disease using a combination blister pack are also disclosed (See Page 5, Lines 1-6).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of Källgren, Depui *et al.*, and Eek into the objects of the instantly claimed invention. It is the position of the examiner that one of ordinary skill would be motivated to combine the disclosures of Källgren, Depui *et al.*, and Eek in order to create a packaging system comprising a proton pump inhibitor in combination with a non-steroidal anti-inflammatory drug. As stated in Depui *et al.*, the administration of a non-steroidal anti-inflammatory drug in combination with a proton-pump inhibitor is known and that patient compliance is a main factor in devising a successful treatment. It is the position of the examiner that similarly, a combination dosage regimen given in a packaging system designed for that purpose, as disclosed in Källgren and Eek, will also lead to greater patient compliance. It is the position of the examiner that one of ordinary skill in the art that would recognize that the aims of

the Källgren, Depui *et al.*, and Eek are similar in the area of improving patient compliance. As the disclosed invention of Källgren is not limited to any particular types of drugs to be packaged, one of ordinary skill can expect to create a drug pack comprising dosages of lansoprazole and naproxen in accordance with a combination dosage regimen with a reasonable expectation of success.

Thus, the instantly disclosed invention is prima facie obvious

***Response to Arguments***

Applicant's arguments filed 20 April 2006 have been fully considered but they are moot in view of the new ground of rejection detailed above. The examiner appreciates the efforts by the applicant to amend the claims to more clearly define the instantly claimed invention. However, after careful consideration of the scope of the instantly claimed invention and the full breadth of the disclosure of the prior art, it is the position of the examiner that the applicant has claimed a known drug combination in known dosage amounts into a known drug packaging system, as disclosed by the prior art. Therefore, the examiner rejects the instantly claimed invention over the prior art.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh
Examiner
Art Unit 1618

sjo

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER